

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Oral Argument Requested

**TORRENT'S OPPOSITION TO PLAINTIFFS'
MOTION TO EXCLUDE OPINIONS OF MARK ROBBINS, PH.D.**

TABLE OF CONTENTS

INTRODUCTION	1
ARGUMENT	3
I. DR. ROBBINS’S ROLE IN THIS CASE IS TO REBUT THE IMPROPER OPINIONS OFFERED BY MR. QUICK.....	3
II. DR. ROBBINS OFFERS RELIABLE AND HELPFUL EXPERT OPINIONS BASED ON HIS EXTENSIVE INDUSTRY EXPERIENCE.....	6
A. Dr. Robbins’s Extensive Industry Experience Qualifies Him as an Expert.....	7
B. Dr. Robbins Identifies and Applies Relevant Industry Standards.....	9
C. Dr. Robbins’s Opinions Provide Context to Help Evaluate Torrent’s Compliance with CGMP.....	12
III. PLAINTIFFS’ REMAINING CRITICISMS OF DR. ROBBINS’S OPINIONS GOES TO THE WEIGHT, NOT ADMISSIBILITY OF HIS OPINIONS.	13
IV. DR. ROBBINS ADEQUATELY SUPERVISED ASSISTANTS AND DRAFTED HIS REPORT.	19
CONCLUSION	24

TABLE OF AUTHORITIES

	Page(s)
 Cases	
<i>Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.</i> , 829 F. Supp. 2d 802 (D. Minn. 2011).....	3
<i>Bank of New York Mellon v. WMC Mortg., LLC</i> , No. 12CV7096, 2015 WL 4887446 (S.D.N.Y. Aug. 17, 2015)	22, 23
<i>Berkeley Inv. Grp., Ltd. v. Colkitt</i> , 455 F.3d 195 (3d Cir. 2006)	4
<i>Breidor v. Sears, Roebuck and Co.</i> , 722 F.2d 1134 (3d Cir. 1983)	14
<i>Casper v. SMG</i> , 389 F. Supp. 2d 618 (D.N.J. 2005)	5
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993).....	<i>passim</i>
<i>Holman Enters. v. Fid. & Guar. Ins. Co.</i> , 563 F. Supp. 2d 467 (D.N.J. 2008)	4, 5
<i>In re Initial Public Offering Sec. Lit.</i> , 174 F. Supp. 2d 61 (S.D.N.Y. 2001)	5
<i>Krys v. Aaron</i> , 112 F. Supp. 3d 181 (D.N.J. 2015)	7
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999).....	9
<i>In re M/V MSC Flaminia</i> , No. 12-CV-8892, 2017 WL 3208598 (S.D.N.Y. July 28, 2017).....	19, 20
<i>Metavante Corp. v. Emigrant Sav. Bank</i> , 619 F.3d 748 (7th Cir. 2010)	13
<i>Numantics, Inc. v. Balluff, Inc.</i> , 66 F. Supp. 3d 934 (E.D. Mich. 2014)	21

<i>Pacific Life Ins. Co. v. Bank of New York Mellon</i> , No. 17 CIV. 1388, 2021 WL 5299193 (S.D.N.Y. Nov. 15, 2021).....	23
<i>Potoski v. Wilkes Univ.</i> , 2010 WL 3811973 (M.D. Pa. Sept. 22, 2010).....	14
<i>In re Rezulin Prods. Liab. Litig.</i> , 309 F. Supp. 2d 531 (S.D.N.Y. 2004)	5
<i>Robinson v. Ethicon, Inc.</i> , No. CV H-20-03760, 2022 WL 614919 (S.D. Tex. Mar. 2, 2022)	5
<i>Stanley v. Novartis Pharms. Corp.</i> , No. CV 11-03191, 2014 WL 12573393 (C.D. Cal. May 6, 2014).....	5
<i>In re Tropicana Orange Juice Mktg. & Sales Pracs. Litig.</i> , No. CV 2:11-07382, 2017 WL 2362848 (D.N.J. May 31, 2017).....	12
<i>Tsao v. Ferring Pharms., Inc.</i> , No. 4:16-cv-01724, 2018 WL 3649714 (S.D. Tex. Apr. 19, 2018), 2018 WL 3589082 (S.D. Tex. June 13, 2018).....	5
<i>In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prods. Liab.</i> <i>Litig.</i> , No. 2:12-cv-07263, 2016 WL 4039324 (E.D. Pa. July 27, 2016).....	5
<i>UGI Sunbury LLC v. A Permanent Easement for 0.4308 Acres</i> , No. 3:16-CV-00794, 2021 WL 5140050 (M.D. Pa. Nov. 4, 2021).....	15, 17
<i>United States v. Brown</i> , 415 F.3d 1257 (11th Cir. 2005)	13
<i>United States v. Care Alts.</i> , 952 F.3d 89 (3d Cir. 2020)	14
<i>United States v. Fernandez</i> , 795 F. App'x 153 (3d Cir. 2020)	10
<i>United States v. Li</i> , 819 F. App'x 111 (3d Cir. 2020)	9, 12
<i>United States v. Vaghari</i> , 735 F. Supp. 2d 197 (E.D. Pa. 2010).....	14

Walker v. Gordon,
46 F.App’x 691 (3d Cir. 2002)14, 19

Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.,
No. CV 15-6480, 2021 WL 2352016 (E.D. Pa. June 9, 2021).....3

In re Zurn Pex Plumbing Liab. Litig.,
644 F.3d 604 (8th Cir. 2011)12

Statutes

Federal Food, Drug, and Cosmetics Act..... 1

Rules

Fed. R. Civ. P. 2312

Fed. R. Civ. P. 26(a)(2)(D)(ii)3, 4, 24

Fed. R. Evid. 7022, 7, 9

Fed. R. Evid. 7039

INTRODUCTION

Plaintiffs’ motion to exclude the opinions of Dr. Mark Robbins is both improper and unsupported and only underscores that Plaintiffs’ own expert, John Quick, should be excluded.

In support of class certification for the consumer economic loss class, Plaintiffs designated Mr. Quick to offer expert opinions regarding the Manufacturer Defendants’ compliance with the Federal Food, Drug, and Cosmetics Act (“FDCA”) and current Good Manufacturing Practices (“CGMP”) regulations in the manufacture of valsartan products. (*See* Quick Rep. ¶ 1).¹ Mr. Quick’s opinions are rife with improper regulatory conclusions as to each of the Manufacturing Defendants’ compliance with the FDCA and CGMP regulations. While Torrent believes that Mr. Quick’s testimony should be excluded, Torrent could not leave Mr. Quick’s opinions unexamined or unrebutted. As a result, Torrent retained Dr. Robbins to critique Mr. Quick’s report, and to advance an admissible evaluation of Torrent’s CGMP practices discussed in Mr. Quick’s report based on Dr. Robbins’s extensive experience in the pharmaceutical manufacturing industry.

¹ The Expert Declaration of John L. Quick (“Quick Rep.”) is attached hereto as **Exhibit 1**.

Once Mr. Quick's testimony is stricken, it may well be the case that the need for Dr. Robbins's testimony goes away as well.² But that is not the subject of this motion. The question in this motion is whether Dr. Robbins's testimony satisfies the requirements of Federal Rule of Evidence 702 and Third Circuit precedent applying that rule. Dr. Robbins's opinions satisfy those requirements for two main reasons.

First, Dr. Robbins's role in this case is to rebut the improper legal and regulatory opinions offered by Mr. Quick, using industry practice and experience. Dr. Robbins's testimony and report are proper, reliable expert witness opinions that will assist the trier of fact on certain CGMP and regulatory issues as they relate to Torrent specifically. *Second*, Plaintiffs' arguments go to the weight of Dr. Robbins's testimony, not its admissibility, and mischaracterize open factual questions as settled matters. To the extent Plaintiffs disagree with Dr. Robbins's opinions, they can address it properly in cross-examination.

For these reasons, discussed further below, Torrent respectfully requests that the Court deny Plaintiffs' motion to exclude Dr. Robbins's opinions.

² In the event that the Court grants Defendants' motion to exclude Mr. Quick's testimony, Torrent will withdraw the testimony of Dr. Robbins.

ARGUMENT

I. DR. ROBBINS’S ROLE IN THIS CASE IS TO REBUT THE IMPROPER OPINIONS OFFERED BY MR. QUICK.

Plaintiffs argue that Dr. Robbins’ opinions do not “fit” this case because [REDACTED]. (ECF No. 2045-1, at 5). Plaintiffs ignore the fact the Dr. Robbins was retained specifically to rebut the impermissible opinions offered by their own expert, Mr. Quick.

Rule 26(a)(2)(D)(ii) permits expert testimony “solely to contradict or rebut evidence on the same subject matter identified by another party[.]” *Winn-Dixie Stores, Inc. v. E. Mushroom Mktg. Coop.*, No. CV 15-6480, 2021 WL 2352016, at *14 (E.D. Pa. June 9, 2021); *see also Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011) (“It is the proper role of rebuttal experts to critique plaintiffs’ expert’s methodologies and point out potential flaws in the plaintiff’s experts’ reports.”). Notably, as a rebuttal expert, Dr. Robbins acknowledged that the scope of his opinions offered is limited to [REDACTED] (Robbins Rep. ¶ 11.³)

³ The Expert Report of Dr. Mark Robbins (“Robbins Rep.”) is attached hereto as **Exhibit 2**.

During his deposition, Dr. Robbins repeatedly confirmed the scope of his assignment:

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(Ex. 3, Robbins Tr. 62:17-23, *see also* 61:13-16, 68:10-16, 71:8-13, 72:13-21, 73:6-8, 97:23-25.) This is proper testimony under Rule 26(a)(2)(D)(ii).

Plaintiffs' expert, Mr. Quick, offered impermissible opinions regarding each of the manufacturing defendants with respect to compliance with CGMP and other regulatory requirements. Dr. Robbins's testimony is that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] ECF No. 2045-1, at 5; Ex. 3, Robbins Tr. 196:12-14).

It is well settled precedent in the Third Circuit that experts may not offer opinions on regulatory law because this oversteps the role of an expert, and usurps the role of the Court and the finder of fact. *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). This principle is "so well established that it is often deemed a basic premise or assumption of evidence law—a kind of axiomatic principle." *Holman Enters. v. Fid. & Guar. Ins. Co.*, 563 F. Supp. 2d 467, 472 (D.N.J. 2008)

(citing *Casper v. SMG*, 389 F. Supp. 2d 618, 621 (D.N.J. 2005) (quoting *In re Initial Public Offering Sec. Lit.*, 174 F. Supp. 2d 61, 64 (S.D.N.Y. 2001)). Indeed, every circuit has explicitly held that experts may not offer opinions that reach legal conclusions. *Id.*

This principle has been consistently applied in the pharmaceutical industry as well. *See, e.g., Robinson v. Ethicon, Inc.*, No. CV H-20-03760, 2022 WL 614919 (S.D. Tex. Mar. 2, 2022) (regulatory expert prohibited from offering opinions that product was misbranded or adulterated, as these are impermissible legal conclusions); *In re: Tylenol (Acetaminophen) Mktg., Sales Pracs., & Prods. Liab. Litig.*, No. 2:12-cv-07263, 2016 WL 4039324, at *4-5 (E.D. Pa. July 27, 2016) (excluding an expert opinion as to whether a drug met a certain standard pursuant to FDA regulations, as such “would require a legal interpretation” of that standard); *Tsao v. Ferring Pharms., Inc.*, No. 4:16-cv-01724, 2018 WL 3649714, at *11-14 (S.D. Tex. Apr. 19, 2018), *adopting R&R in relevant part*, 2018 WL 3589082 (S.D. Tex. June 13, 2018) (opinion by regulatory expert that drug was “misbranded” was “inadmissible legal conclusion[.]”); *Stanley v. Novartis Pharms. Corp.*, No. CV 11-03191, 2014 WL 12573393, at *4 (C.D. Cal. May 6, 2014) (precluding an expert from “offer[ing] legal conclusions, including whether Defendant was in regulatory compliance with the FDA”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004) (holding that opinions regarding “the duties of pharmaceutical

companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert”).

Mr. Quick’s report violates this black letter law and is rife with improper legal and regulatory testimony. (*See, e.g.*, Quick Rep. ¶ 29 (concluding that Defendants’ valsartan products were adulterated based on the fact that in Mr. Quick’s view, the valsartan products were manufactured in “facilities that did not have the appropriate CGMP quality assurance activities in place.”)); (*see also id.* ¶ 28 (“The fact that NDMA and/or NDEA (and other contaminants) were present in the API and ultimately in the finished drug product results in the product . . . being adulterated.”)). As to Torrent specifically, Mr. Quick [REDACTED]

[REDACTED]. (Quick Rep. ¶¶ 155-166).

While Torrent believes that Mr. Quick’s impermissible expert testimony should and will be excluded, until there is a ruling on Defendants’ motion to exclude, Torrent felt compelled to offer rebuttal expert testimony, and thus engaged Dr. Robbins.

II. DR. ROBBINS OFFERS RELIABLE AND HELPFUL EXPERT OPINIONS BASED ON HIS EXTENSIVE INDUSTRY EXPERIENCE.

Despite Plaintiffs’ mischaracterization of Dr. Robbins’ report and testimony, Dr. Robbins does not offer an opinion regarding [REDACTED]

(ECF No. 2045-1, at 5; Robbins Tr. 196:12-14). Rather, in rebuttal to Mr. Quick's improper expert testimony, Dr. Robbins offers expert opinions regarding [REDACTED]

[REDACTED]. (Robbins Rep. ¶¶ 13-17). His opinions on these topics meet the threshold for the admissibility of an expert's opinion, as "(1) [Dr. Robbins's] knowledge will assist the factfinder in understanding the evidence or an issue of fact; (2) [his] testimony relies upon sufficient facts or data; (3) [his] testimony resulted from 'reliable principles and methods; and (4) [Dr. Robbins] 'reliably applied the principles and methods to the facts of the case.'"" *Krys v. Aaron*, 112 F. Supp. 3d 181, 189 (D.N.J. 2015) (quoting Fed. R. Evid. 702).

A. Dr. Robbins's Extensive Industry Experience Qualifies Him as an Expert.

Dr. Robbins undoubtedly satisfies the qualification requirements of Rule 702, which Plaintiffs do not dispute. Dr. Robbins has over forty years of experience in the pharmaceutical and biotechnology industries that qualify him to offer expert testimony in this matter. [REDACTED]

[REDACTED]

[REDACTED]. (Robbins Rep. ¶ 8.)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*)

[REDACTED]

[REDACTED]. (Robbins Rep. ¶ 3.) [REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

[REDACTED] (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED] (Robbins Rep. ¶¶ 3-8). [REDACTED]

[REDACTED]

[REDACTED]

██████████. (Robbins Rep. ¶¶ 13-17).

B. Dr. Robbins Identifies and Applies Relevant Industry Standards.

Contrary to Mr. Quick, Dr. Robbins ██████████. (*See* Robbins Tr. 103:9-16.) Instead, Dr. Robbins properly bases his opinions on his experience and industry standards. “[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993) (citing Fed. R. Evid. 702 & 703). Expert testimony may be based on personal knowledge or experience, and in those circumstances the Court may inquire into whether the expertise is based on generally accepted methods and training. *United States v. Li*, 819 F. App’x 111, 117–18 (3d Cir. 2020) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150–51 (1999)). In *Li*, the Third Circuit affirmed the District Court’s ruling allowing a doctor to offer expert opinions on the medical standards for pain management where the opinions were grounded in the expert’s thirty years of experience as a pain management doctor, as well as medical studies, and state policies and regulations. *Id.* at 118. Dr. Robbins’s opinions ██████████

██████████. (*See e.g.*, Robbins Rep. ¶¶ 48-50, 59, 66-67.)

Plaintiffs’ argument that Dr. Robbins’s opinion is unreliable because he did

not review certain documents underlying the relationship between Torrent and its API supplier, ZHP, is misplaced. (*See* ECF No. 2045-1, at 6-8). Dr. Robbins does not need to review every underlying document to form his opinions offered to rebut Mr. Quick. *See, e.g., United States v. Fernandez*, 795 F. App'x 153, 155 n.14 (3d Cir. 2020) (“Although [defendant] asserts error because [the Government’s expert] lacked specific and personal case knowledge, a qualified expert need not have personal knowledge of a matter, and he ‘may base an opinion on facts or data in the case that the expert has been made aware of.’ Nor did the District Court abuse its discretion in permitting [the expert]’s general testimony because he did not review case reports or specifically address the mental states of defendants.” (internal citations omitted.))

Dr. Robbins’s opinions are properly based on his industry experience and are

[REDACTED]

(Robbins Rep. ¶ 48.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(Robbins Tr. 165:7-166:11).

In fact, Dr. Robbins based his analysis first and foremost on the same set of documents that Mr. Quick relied upon, and focused his opinions on [REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]

(Robbins Tr. 164:14-165:3). Plaintiffs' argument demonstrates that their own

expert, Mr. Quick, has not reviewed the documents they argue Dr. Robbins needed to have reviewed.

Dr. Robbins's methodology is squarely in line with precedent in the Third Circuit recognizing that expert opinions may be reliably based on the expert's knowledge and experience in the expert's field of expertise. *See Li*, 819 F. App'x at 117–18.

C. Dr. Robbins's Opinions Provide Context to Help Evaluate Torrent's Compliance with CGMP.

Dr. Robbins's report and testimony will be useful to the finder of fact in multiple ways. For example, Dr. Robbins's expert testimony regarding the regulatory process for generic drugs, including his overview of CGMP regulations, will be helpful in assessing Torrent's practices surrounding the manufacturing of valsartan products. It will also be helpful in determining the weight that should be given to Mr. Quick's opinions, and will help avoid confusion or overreliance on Mr. Quick's questionable expert testimony.

Further, concerns about whether or not an expert's opinions are helpful to the trier of fact are lessened in the context of Rule 23. “The main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious [expert] testimony.” *See In re Zurn Pex Plumbing Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011). The trial court's “gatekeeping function” is, therefore, reduced “when the gatekeeper is keeping the gate only for himself.” *In re Tropicana Orange Juice*

Mktg. & Sales Pracs. Litig., No. CV 2:11-07382, 2017 WL 2362848, at *2 (D.N.J. May 31, 2017) (quoting *United States v. Brown*, 415 F.3d 1257, 1269 (11th Cir. 2005)); see also *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 760 (7th Cir. 2010) (stating that the “usual concerns” of *Daubert*— i.e., “keeping unreliable expert testimony from the jury” —are not present during a bench trial). “At class certification, the district court serves as the trier-of-fact and no jury is present. Accordingly, the Court will weigh the parties' expert challenges in light of this consideration.” *Id.*

Throughout his engagement, Dr. Robbins has stayed within the bounds of proper expert witness testimony and provided helpful and reliable opinions based on decades of industry experience and practice.

III. PLAINTIFFS' REMAINING CRITICISMS OF DR. ROBBINS'S OPINIONS GOES TO THE WEIGHT, NOT ADMISSIBILITY OF HIS OPINIONS.

Despite Plaintiffs' efforts to characterize their arguments as a challenge to Dr. Robbins's methodology, Plaintiffs' motion is merely a recitation of their view of the merits of this case. (*See, e.g.*, ECF No. 2045-1, at 8-11.) While Plaintiffs' recitation is wrong on the merits, the larger point is that these arguments are legally insufficient to justify the exclusion of Dr. Robbins's opinions.

“With respect to expert opinion testimony, as in other areas of evidence law, it is axiomatic that ‘vigorous cross-examination, presentation of contrary evidence,

and careful instruction on the burden of proof are the traditional and appropriate means” of attacking expert opinions a party disagrees with. *United States v. Vaghari*, 735 F. Supp. 2d 197, 206 (E.D. Pa. 2010) (quoting *Daubert*, 509 U.S. at 595.) To the extent Plaintiffs disagree with Dr. Robbins’s conclusions, Plaintiffs can cross-examine Dr. Robbins on those issues, and the Court can decide how much weight to afford Dr. Robbins’s opinions. *See Potoski v. Wilkes Univ.*, 2010 WL 3811973, at *6 (M.D. Pa. Sept. 22, 2010) (finding that “determinations regarding the weight to be afforded to an expert’s conclusions, and the sufficiency of the evidence relied upon by the proffered expert, are within the sole province of the jury.”); *United States v. Care Alts.*, 952 F.3d 89, 98 (3d Cir. 2020) (The “reliability and believability of expert testimony ... is exclusively for the jury to decide.”); *Breidor v. Sears, Roebuck and Co.*, 722 F.2d 1134, 1138–39 (3d Cir. 1983) (“Where there is a logical basis for an expert’s opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge.”).

Plaintiffs’ argument that Dr. Robbins’s opinions must be excluded as “unreliable” because they are factually incorrect is simply a recitation of Plaintiffs’ assertions that 1) Torrent unreasonably delayed recalling its Valsartan products; and 2) Torrent violated CGMPs. (ECF No. 2045-1, at 8-9.) Neither of these can be accepted as “fact,” and neither justifies excluding Dr. Robbins. *See Walker v. Gordon*, 46 F.App’x 691, 695–96 (3d Cir. 2002) (“An expert is, nonetheless,

permitted to base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion is for the jury.”); *UGI Sunbury LLC v. A Permanent Easement for 0.4308 Acres*, No. 3:16-CV-00794, 2021 WL 5140050, at *10 (M.D. Pa. Nov. 4, 2021) (finding that a disagreement between each party’s experts as to the correct interpretation of a contractual provision is “a factual dispute for the trier of fact to resolve, not a reason to exclude expert testimony”).

A. Plaintiffs Ignore Factual Disputes Regarding Torrent’s Valsartan Recall.

With respect to the reasonableness of the recall, deposition testimony clearly establishes that there were valid justifications and explanations unpinning Torrent’s actions. As Dawn Chitty, former Vice President of Strategy and Scientific Affairs at Torrent Pharma Inc. explained, [REDACTED]

[REDACTED]. (Ex. 4, Chitty Tr. 147:4-9, 279:1-7 [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (*See id.* at 198:7-16, 264:16-19 [REDACTED]

[REDACTED]), 266:13-

24 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (Ex. 5, Torrent Ex. 91, at 2-5.)

Ms. Chitty also explained that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (Chitty Tr. 296:14-21); *see also id.* at 303:10-15 (“ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(*Id.* at 436:14-437:3). Neither Mr. Quick’s report nor Plaintiffs’ motion to exclude Dr. Robbins’s opinions engage with these facts supporting why Torrent chose to recall valsartan when it did. Plaintiffs’ motion also fails to acknowledge that Dr. Robbins’ opinion [REDACTED]

[REDACTED] (*See* Robbins Tr. at 270:11-271:11). Instead, Plaintiffs’ motion relies on an assumption that Torrent, as a matter of fact, unreasonably delayed in initiating a recall, and argues that Dr. Robbins should be excluded for failing to accept this assumption. (ECF No. 2045-1, at 8-9.) Whether or not Torrent unreasonably delayed its recall is a question of fact, and does not bear on the admissibility of Dr. Robbins’s opinions. *UGI Sunbury LLC v. A Permanent Easement for 0.4308 Acres*, No. 3:16-CV-00794, 2021 WL 5140050, at *10 (M.D. Pa. Nov. 4, 2021) (finding that a disagreement between each party’s experts as to the correct interpretation of a contractual provision is “a factual dispute for the trier of fact to resolve, not a reason to exclude expert testimony”).

B. Plaintiffs' Argument Assumes Torrent's Noncompliance with CGMP as Fact.

With respect to whether or not Torrent was in compliance with CGMP requirements, Plaintiffs' argument relies solely on a single email [REDACTED] [REDACTED]. (ECF No. 2045-1, at 11-12.) As a threshold matter, Plaintiffs mischaracterize Dr. Robbins's reliance on this document, stating that it is "[t]he only document that Dr. Robbins relied on to [REDACTED] [REDACTED]." (ECF No. 2045-1, at 11). In reality, Dr. Robbins relied on the [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] (Ex. 6, 12/22/20 Letter from A. Brancato re Torrent 30(b)(6) Designations), [REDACTED] (Robbins Rep. ¶ 59.) [REDACTED] [REDACTED]. (Robbins Rep. ¶ 59 n.80.)

Plaintiffs then proceeded to make a number of baseless assumptions and arguments based on [REDACTED] [REDACTED]

[REDACTED] and 3) because Dr. Robbins was unfamiliar with the context surrounding this particular email, his opinion on [REDACTED] [REDACTED] is contradicted by the factual record, and should therefore be excluded. (ECF No. 2045-1, at 8-9, 11-12). But once again, these are simple factual disputes that are irrelevant to a *Daubert* analysis. And whether or not Dr. Robbins considered the context of one email does not bear on the admissibility of his testimony.⁴ *Walker*, 46 F. App'x at 695–96.

IV. DR. ROBBINS ADEQUATELY SUPERVISED ASSISTANTS AND DRAFTED HIS REPORT.

Plaintiffs' last-ditch argument is that Dr. Robbins's opinions should be excluded because he improperly relied on support from Analysis Group. This argument is meritless. As Plaintiffs correctly note, the rules of evidence "allow an expert to present the work of others if the expert supervised, directed, or participated in that work, and if the expert is qualified in the field and could perform the work

⁴ Plaintiffs' view also ignores other evidence in the record, including that Torrent's Indrad facility regularly passed FDA inspections, and that the Warning Letter Plaintiffs cite postdates the recall and is unrelated to API testing or trace impurities in Torrent's products. *See* Ex. 7, "Inspection Classification Database," FDA, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-classification-database>; Ex. 8, "Warning Letter, Torrent Pharmaceuticals Limited, MARCS-CMS 585255 — OCTOBER 08, 2019," available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019>.

themselves.” *In re M/V MSC Flaminia*, No. 12-CV-8892, 2017 WL 3208598, at *2 (S.D.N.Y. July 28, 2017). However, Plaintiffs’ reliance on *Flaminia* is misplaced. In *Flaminia*, the court excluded expert testimony where an expert on “the investigation of fires and explosions” proffered testimony regarding chemistry, heat transfer and temperature determinations, metallurgy, proper release of CO₂, and shipping regulations and stowage. *Id.* at *19-21. Because the expert had no background on these topics and could not independently confirm his opinions without relying on others, his testimony was excluded. *Id.* at *22-23. There is no such concern with Dr. Robbins. The invoices provided by Analysis Group confirm that not only was the work performed by Analysis Group appropriate work to be performed by support staff, they also demonstrate that Dr. Robbins could perform the work himself. (*See* Ex. 9, Robbins Ex. 8, AG Invoice.) (reflecting that Analysis Group assisted with tasks such as research, reviewing deposition testimony, and editing Dr. Robbins’s report). Further, Dr. Robbins’s sworn deposition testimony

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(Robbins Tr. 79:22-80:8).

Plaintiffs also point to the length of Dr. Robbins's report relative to the number of hours he billed for his work as evidence that he could not possibly have written his report. [REDACTED]

[REDACTED]

Dr. Robbins's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(Robbins Tr. 93:8-23).

Plaintiffs' reliance upon *Numantics, Inc. v. Balluff, Inc.*, 66 F. Supp. 3d 934 (E.D. Mich. 2014) is misplaced. There, the court excluded an expert because it "d[id] not appear to be contested" that defendant's counsel wrote the expert's report, and the expert "d[id] not furnish a basis for his invalidity analysis, d[id] not tether his factual experience to his opinions, and relie[d] on [defendant's] counsel for his

analysis.” *Id.* at 941-42. This is in stark contrast to Dr. Robbins’s report and deposition. At his deposition, Dr. Robbins [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (See Robbins Tr. 111:14-21, 112:10-23, 122:10-15, 158:4-159:11, 162:15-163:17.)

Plaintiffs’ next citation, *Bank of New York Mellon v. WMC Mortg., LLC*, No. 12CV7096, 2015 WL 4887446 (S.D.N.Y. Aug. 17, 2015), is inapposite. There, the plaintiff offered an expert to opine on whether certain loans violated certain representations and warranties between the parties. *Id.* at *3. While the expert and his team reviewed a portion of the loan files, a third party, not under the supervision of the expert, reviewed the majority of the loan files. *Id.* at *3-4. The court ultimately excluded his testimony in part, finding that his opinions on the loans reviewed by the third party were inadmissible except for a subset of those loans that the expert and his team reviewed. *Id.* at *9. Notably, Plaintiffs do not clarify that the reunderwriters that the court found the expert failed to supervise were a third party, and that the expert’s opinion based on loans reviewed by the expert and his team were not excluded. (ECF No. 2045-1, at 20). Here, there is no third party distinct from Dr. Robbins and his supporting team at Analysis Group. Dr. Robbins

[REDACTED]

██████████. (Robbins Rep. ¶ 11). At his deposition, Dr. Robbins ██████████ (see, e.g., Robbins Tr. 79:1-4, 80:4-8, 81:13-18), in stark contrast to the brief call the expert had with the third party in *Bank of New York Mellon*. *Bank of New York Mellon*, 2015 WL 4887446 at *6. The circumstances in *Bank of New York Mellon* are inapposite.

Pacific Life Ins. Co. v. Bank of New York Mellon, No. 17 CIV. 1388, 2021 WL 5299193 (S.D.N.Y. Nov. 15, 2021), is likewise inapposite. In *Pacific Life*, the court affirmed the exclusion of an expert who “could not even recall whether he personally wrote an initial draft of the report or whether the draft had been sent to him by someone else.” *Id.* at *5. Here, Dr. Robbins ██████████ ██████████. (Robbins Tr. 80:4-8). And unlike the expert at issue in *Pacific Life*, Dr. Robbins’s ██████████ ██████████. (Robbins Tr. 79:1-4, 80:4-8, 81:13-18).

Plaintiffs also allege that Dr. Robbins’s apparent unfamiliarity with certain documents shows that Dr. Robbins did not write his report. As an initial matter, Plaintiffs mischaracterize Dr. Robbins’s use of certain documents, claiming in their brief that Dr. Robbins was unfamiliar with multiple documents “cited” in his brief when in fact many of those documents were not documents Dr. Robbins cited in his report, but rather documents included on his list of materials relied upon. (ECF

No. 2045-1, at 13-15). But in any event, a deposition is not a memory test, and Dr. Robbins's inability to recall all 113 documents included on his list of materials relied upon is not proper grounds to exclude his testimony.

Plaintiffs also selectively omit occasions where Dr. Robbins was able to refresh his recollection after having the opportunity to review the document. For example, Plaintiffs selectively cite Dr. Robbins's [REDACTED]

[REDACTED]. (ECF No. 2045-1, at 15-16.) Plaintiffs ignore Dr. Robbins's testimony a few pages later, [REDACTED]

[REDACTED] (See Robbins Tr. 191:18-24.)

At bottom, Dr. Robbins indisputably meets the requirements to offer rebuttal testimony under Rule 26(a)(2)(D)(ii).

CONCLUSION

For foregoing reasons, Torrent respectfully requests that the Court deny Plaintiffs' motion to exclude the opinions of Torrent's expert Dr. Mark Robbins.

Dated: June 2, 2022

Respectfully Submitted:

By: /s/ Alexia R. Brancato

KIRKLAND & ELLIS LLP
Devora W. Allon
Alexia R. Brancato
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
Devora.allon@kirkland.com
Alexia.brancato@kirkland.com

*Attorneys for Torrent
Pharmaceuticals Ltd. and Torrent
Pharma Inc.*

CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on June 2, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Alexia R. Brancato

Alexia R. Brancato
Kirkland & Ellis LLP